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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/661,809	09/15/2003	Magnus Hook	P07741US01/BAS	7385

881 7590 03/20/2006

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EXAMINER	
SMITH, CAROLYN L	

ART UNIT	PAPER NUMBER
1631	

DATE MAILED: 03/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/661,809	HOOK ET AL.	
	Examiner	Art Unit	
	Carolyn L. Smith	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-40* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-40* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR § 1.821 (a)(1) and (a)(2). See for example, pages 21 (Table 3) and 60. However, this application fails to comply with the requirements of 37 CFR § 1.821 through 1.825, because it lacks SEQ ID Nos cited along with each sequence in the above mentioned pages of the specification. Applicant(s) are required to submit a new computer readable form sequence listing, and a paper copy, or CD-ROM incorporated by reference into the specification, statements under 37 CFR § 1.821 (f) and (g), if there is a need to list additional sequences in the sequence listing. Applicant(s) are given the same response time regarding this failure to comply as that set forth to respond to this office action. Failure to respond to this requirement may result in abandonment of the instant application or a notice of a failure to fully respond to this Office Action.

Restriction/Election

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-5, drawn to a method of identifying LPXTG-containing cell wall-anchored surface proteins from Gram positive bacteria that bind to an extracellular matrix molecule via sequence analysis involving one or more IG-like fold regions, classified in class 702, subclass 19. If this Group is elected, then the below summarized specie election is also required.

II. Claims 6-8, 12-13, 16, 29-30, and 38, drawn to proteins and pharmaceutical compositions comprising proteins, classified in class 530, subclass 350 and class 514, subclass 1. If this Group is elected, then the below summarized sequence election is also required.

III. Claims 9, 14, 19-26, and 28, drawn to antibodies, antisera, a kit, and a pharmaceutical composition comprising an antibody, classified in class 530, subclass 387.1; class 424, subclass 130.1; class 422, subclass 61; and class 514, subclass 1. If this Group is elected, then the below summarized sequence election is also required.

IV. Claims 10, 15, and 17-18, drawn to nucleic acids, classified in class 536, subclass 23.1. If this Group is elected, then the below summarized sequence election is also required.

V. Claim 11, drawn to a method of identifying LPXTG-containing cell wall-anchored surface proteins from Gram positive bacteria that bind to an extracellular matrix molecule via sequence analysis involving a signal peptide at the N-terminus, the C-terminus followed by a hydrophobic transmembrane segment, and several positively charged residues at the C-terminus, classified in class 702, subclass 20.

VI. Claims 27 and 31, drawn to a method of treating or preventing an infection of a Gram positive bacteria via antibody administration, classified in class 436, subclass 547. If this Group is elected, then the below summarized sequence election is also required.

VII. Claim 32, drawn to a method of diagnosing an infection caused by Gram positive bacteria via antibody introduction, classified in class 435, subclass 7.1. If this Group is elected, then the below summarized sequence election is also required.

VIII. Claims 33 and 40, drawn to a method of eliciting an immunogenic reaction, classified in class 514, subclass 2. If this Group is elected, then the below summarized sequence election is also required.

IX. Claim 34, drawn to a vaccine, classified in class 424, subclass 184.1. If this Group is elected, then the below summarized sequence election is also required.

X. Claims 35-36, drawn to a method of assaying for the presence of antigens from Gram positive bacteria via detection of labeled antibody, classified in class 435, subclass 7.32. If this Group is elected, then the below summarized sequence election is also required.

XI. Claim 37, drawn to a method of monitoring the level of Gram positive bacterial antigens via determination of antigen-antibody binding levels, classified in class 435, subclass 7.2. If this Group is elected, then the below summarized sequence election is also required.

XII. Claim 39, drawn to a method of diagnosing an infection caused by Gram positive bacteria via protein introduction, classified in class 435, subclass 7.1. If this Group is elected, then the below summarized sequence election is also required.

Sequence Election Requirement for Groups II-IV and VI-XII:

The claims in this invention read on patentably distinct sequences. Each sequence is patentably distinct because they are unrelated sequences. For amino acid/polypeptide or nucleotide sequences, the Applicants must elect a single nucleic acid sequence (See MPEP 803.04). It is noted that the multitude of sequence submissions of examination has resulted in an undue search burden if more than one nucleic acid sequence is elected, thus making the previous

waiver for up to 10 elected nucleic acid sequences effectively impossible to reasonably implement.

MPEP 803.04 states:

Nucleotide sequences encoding different proteins are structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to normally constitute independent and distinct inventions with the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleotide sequence is presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.141 et seq. Examination will be restricted to only the elected sequence. It is additionally noted that this sequence election requirement is a restriction requirement and not a specie election requirement.

Specie Election Requirement for Group I:

This application contains claims directed to the following patentably distinct species of the claimed invention:

For Group I:

Group I contains patentably distinct species, namely different genera of Gram positive bacteria (as state in instant claims 2 and 3). Therefore, if this Group is elected, it is requested that Applicants select a particular Gram positive bacteria, so that initial examination of this application may proceed.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed specie for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, all claims in Group I are generic to the above species. The distinctness or independence of the various genera of Gram positive bacteria is because each genus has different structural and functional characteristics. All of these species are distinct as described above without overlapping search due to different subject matter. This lack of overlapping searches documents the undue search burden if the species were searched together.

Applicant is advised that a reply to this requirement must include an identification of the specie that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should an applicant traverse the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

The inventions are distinct, each from the other because of the following reasons:

The inventions of Groupings [I, II, V, VIII, IX, XII], [III, VI, VII, X, XI] and [IV] are independent inventions because they are directed to different chemical types regarding the critical limitations therein. For Groups I, II, V, VIII, IX, and XII, the critical feature is a protein. For Groups III, VI, VII, X, and XI, the critical feature is an antibody. For Group IV, the critical feature is a nucleic acid. The completely separate chemical and entity types of the invention Groups are often separately characterized and published in literature, thus adding to the search burden if all Groups were examined together. Also, processing that may connect two Groups does not prevent them from being considered distinct because enough processing can result in the production of any composition from another composition as long as the processing is not limited in occurrences such as subtractions, additions, and enzymatic action. Thus, the three Groupings [I, II, V, VIII, IX, XII], [III, VI, VII, X, XI] and [IV] are independent and/or distinct invention types for restriction purposes.

Inventions in Groups I, II, V, VIII, IX, and XII are related as product and the process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the protein of Group II may be utilized in distinct usages as needed in Group I for identifying LPXTG-containing cell wall-anchored surface proteins from Gram positive bacteria that bind to an extracellular matrix molecule via sequence analysis involving one or more IG-like fold regions, in a method of identifying LPXTG-containing cell wall-anchored surface proteins from Gram positive bacteria

that bind to an extracellular matrix molecule via sequence analysis involving a signal peptide at the N-terminus, the C-terminus followed by a hydrophobic transmembrane segment, and several positively charged residues at the C-terminus as in Group V, in a method of eliciting an immunogenic reaction as in Group VIII, in a vaccine as in Group IX, in a method of diagnosing an infection caused by Gram positive bacteria via protein introduction as in Group XII, or alternatively, in preparing T cells. All of these usages are distinct as requiring distinct and different functions thereof without overlapping search due to divergent subject matter. This lack of overlapping searches documents the undue search burden if they were searched together.

Inventions in Groups III, VI, VII, X, and XI are related as product and the process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibody of Group III may be utilized in distinct usages as needed in Group VI for a method of treating or preventing an infection of a Gram positive bacteria via antibody administration, in a method of diagnosing an infection caused by Gram positive bacteria via antibody introduction as in Group VII, in a method of assaying for the presence of antigens from Gram positive bacteria via detection of labeled antibody as in Group X, in a method of monitoring the level of Gram positive bacterial antigens via determination of antigen-antibody binding levels as in Group XI, or alternatively, in detecting cancer. All of these usages are distinct as requiring distinct and different functions thereof without overlapping search due to divergent subject matter. This lack of overlapping searches documents the undue search burden if they were searched together.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement may be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR §1.6(d)). The Central Fax Center number for official correspondence is (571) 273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carolyn Smith, whose telephone number is (571) 272-0721. The examiner can normally be reached Monday through Thursday from 8 A.M. to 6:30 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, can be reached on (571) 272-0718.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instruments Examiner Tina Plunkett whose telephone number is (571) 272-0549.

March 14, 2006

Carolyn Smith
Examiner
Art Unit 1631